REMARKS

I. PRELIMINARY REMARKS

Claims 31, 33, 55, 65 and 66 have been amended. Claims 70-73 have been added. No claims have been canceled. Claims 30, 31, 33-44, 46-61 and 63-73 remain in the application. Reexamination and reconsideration of the application, as amended, are respectfully requested.

Applicant notes with appreciation that claims 40-44, 46-49, 60, 61, 63, 64 and 67-69 have been allowed and that the Examiner has indicated that claims 31, 33 and 55 would be allowable if rewritten in independent form. As claims 31, 33 and 55 have been rewritten in independent form, applicant respectfully submits that they are also in condition for allowance.

The amendment filed June 11, 2003 included a request for correction of inventorship under 37 C.F.R. § 1.48(b). More specifically, applicant requested that original co-inventors Russell B. Thompson, Sidney D. Fleischman, James G. Whayne, David K. Swanson be deleted. The two subsequent Office Actions have not included any indication that request was considered. Accordingly, applicant respectfully requests that the Examiner consider the request for correction of inventorship and indicate whether or not it has been granted in the next Office Action.

II. REJECTION UNDER 35 U.S.C. § 112

Claim 66 has been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant respectfully submits that the rejection under 35 U.S.C. § 112 has been obviated by the amendment above, that the rejection under 35 U.S.C. § 112 should be withdrawn, and that claim 66 is in condition for allowance.

III. REJECTIONS UNDER 35 U.S.C. § 102

A. The Rejections

Claims 30 and 34 have been rejected under 35 U.S.C. § 102 as being anticipated by the Peacock patent (U.S. Patent No. 6,059,770). Claims 30, 34-39, 50-54 and 56-59 have been rejected under 35 U.S.C. § 102 as being anticipated by the Webster patent (U.S. Patent No. 5,827,278). Claim 65 has been rejected under 35 U.S.C. § 102 as being anticipated by the Berenstein patent (U.S. Patent No. 5,895,378).

The rejections under 35 U.S.C. § 102 are respectfully traversed with respect to the claims as amended above. Reconsideration thereof is respectfully requested.

B. Claim Interpretation Issues Raised By the Office Action

The Office Action has apparently taken the position that Peacock coil 15 and the Webster coil 32 correspond to the claimed "steering center support." For the reasons set forth below, applicant respectfully submits that this position is incorrect. Additionally, should the rejections based on the Peacock and Webster patents be maintained in the next Office Action, applicant respectfully requests that the Examiner ***respond fully to the arguments below*** in order to clarify the issues for appeal.

Claims in an application are to be given their broadest reasonable interpretation. This interpretation must be "consistent with the specification" and "consistent with the one that those skilled in the art would reach." *In re Cortright*, 49 USPQ2d 1464, 1467 (Fed. Cir. 1999). One way to determine the interpretation which one of skill in the art would ascribe to a particular term is to review analogous prior art references. *Vitronics Corp. v. Conceptronic, Inc.*, 39 USPQ2d 1573, 1578-79 (Fed. Cir. 1996) ("prior art can often help to demonstrate how a disputed term is used by those skilled in the art"). As such, "the PTO's interpretation of claim terms should not be so broad that it conflicts with the meaning given to identical terms in other patents from analogous art." *In re Cortright*, 49 USPQ2d at 1467.

With respect to the present application, the specification and drawings make it perfectly clear that a "coil" (such as the Peacock coil 15 or the Webster coil 32) and a "steering center support" are two completely different things. The specification and drawings make this clear both in the context of the prior art and in the context of the present inventions. Referring first to page 2, lines 4-12, when discussing conventional catheters, the "Background of the Inventions" portion of the present specification states:

> Steerable catheters typically include an elongate guide ***coil*** that extends from the proximal end of the catheter to a point proximal to the distal end. The steering mechanism consists primarily of ***a steering center support (also referred to as a "steering spring")*** that extends from the distal end of the guide ***coil*** to the distal tip of the catheter. The inventors herein have determined that the configuration of the steering mechanism in conventional steerable catheters, including the location at which the ***steering wires are attached to the center support***, makes it difficult for conventional catheters to obtain intimate tissue contact.

[Emphasis added.]

Accordingly, the "Background of the Inventions" portion of the specification clearly refers to a "steering center support" and a "coil" as two different things and explains, in manner that one of ordinary skill in the art would certainly understand, that one of these things (i.e. the "steering center support") extends from the other (i.e. the "coil"). This portion of the specification also unambiguously indicates that the applicant, who may be his own lexicographer, has used the term "steering center support" to mean the same thing as "steering spring."

One exemplary embodiment of an invention disclosed in the present application is illustrated in Figure 35, which is reproduced on the following page. The "Detailed Description of the Preferred Embodiments" portion of the specification states that the embodiment illustrated in Figure 35 includes "a proximal member 400, an elongate guide ***coil 402***, and a distal member 404." [Page 22, lines 8-10, emphasis added.] The specification further states that the catheter "includes a distal steering assembly 412 that

consists primarily of a bendable ***steering center support 414*** ... The center support 414 includes a pair of shoulders 416. One of the shoulders is ***inserted into the guide coil 402*** and the other is secured to the tip electrode 408." [Page 22, line 26 to page 23, line 1, emphasis added.] The specification also states that "[s]teering wires 418 are secured to opposing sides of the steering center support 414" and that "[t]he steering wires 418 extend through the guide coil 402 and are connected to a control knob on the catheter handle." [Page 23, line 6-8, emphasis added.]

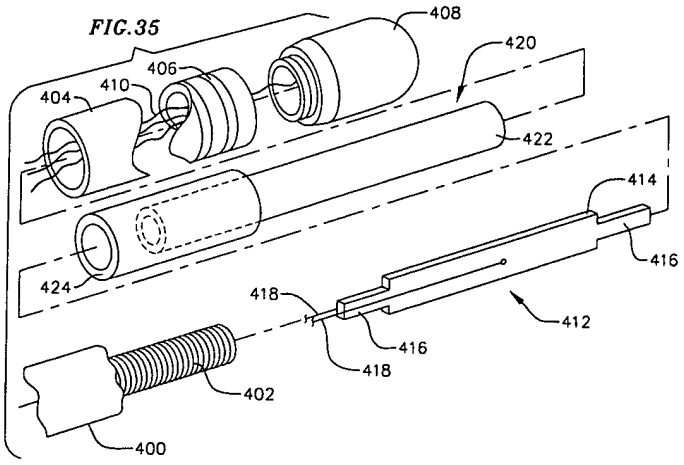

Figure 35 of the Present Application

Accordingly, the "Detailed Description" portion of the specification also clearly refers to a "steering center support" and a "coil" as two different things and explains, in manner that one of ordinary skill in the art would certainly understand, that one of these things (i.e. the "steering center support") is mounted on the other (i.e. the "coil").

The Examiner's interpretation of the phrase "steering center support" also conflicts with the interpretation that those skilled in the art would reach. To that end, attached hereto are three analogous prior art references from the catheter art. Each of the catheter references uses the term "center support" or "steering spring," which page 2 of the specification indicates means the same thing as "center support," in the same manner as the present specification. Moreover, each of these patents clearly differentiates between "coils" and "center supports" (or "steering springs").

U.S. Patent No. 5,358,478 to Thompson ("the Thompson '478 patent"), which is attached hereto as Exhibit 1, uses the term "center support" in the same manner as the

present application. Referring to Figure 4, which is reproduced below, the Thompson '478 patent indicates that the "stiffening spring assembly 90 stiffens the ***center support*** near the distal end of the guide tube shaft 62." [Column 7, lines 4-5, emphasis added.] The center support, which is also referred to as the support wire 78 in the Thompson '478 patent, is connected to a pair of steering wires 56 and 58. [Column 6, lines 41-50.] Additionally, although there are a wide variety of center support configurations disclosed in the present application, it is noteworthy that the center support illustrated in the Thompson '478 patent is essentially identical to center support illustrated in Figure 35, which is reproduced above.

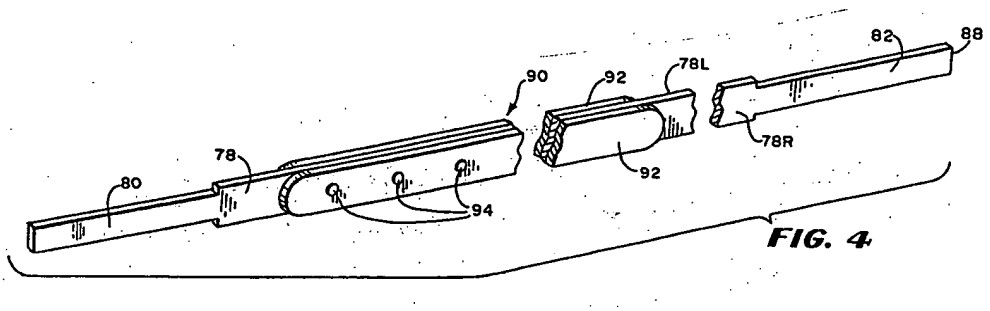

Figure 4 of the Thompson '478 Patent

U.S. Patent No. 6,013,052 to Durman ("the Durman '052 patent") is attached hereto as Exhibit 2. Referring to Figure 6, which is reproduced below, the Durman '052 patent states that "the exemplary catheter body 12 may include a ***coil spring 50*** and a ***steering spring 52*** (such as a flat leaf spring) extending from the distal end of the coil spring to the distal tip of the catheter body" and that "[t]he distal end 60 of the steering wire 22 is secured to steering spring 52 by, for example, a weld 62." [Column 6, lines 26-36.]

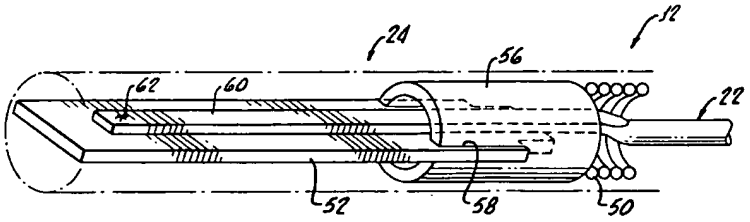

Figure 6 of the Durman '052 Patent

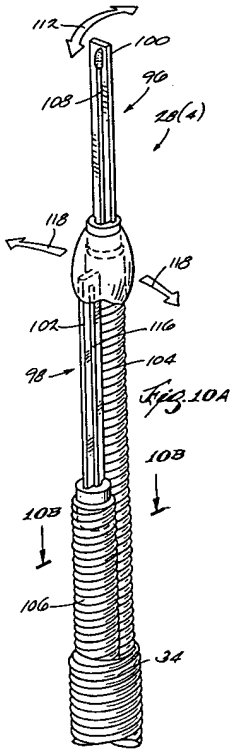

Figure 10A of the Thompson '591 Patent

U.S. Patent No. 5,820,591 to Thompson ("the Thompson '591 patent"), which is attached hereto as Exhibit 3, uses the term "steering spring" in the same manner as the present application. [As noted above, the present specification indicates that "steering center support" means the same thing as "steering spring."]. Referring to Figure 10A, the Thompson '591 patent states that "steering wires 108 and 110 are attached to the opposite sides of the distal ***steering spring 100*** to enable bending in a first plane (shown by arrows 112 in FIG.10A) ... steering wires 114 and 116 are attached to opposite sides of the proximal ***steering spring 102*** to enable bending in a second plane (shown by arrows 118 in FIG. 10A)." [Column 7, lines 52-58.] With respect to the coiled element identified by reference numeral 34, the Thompson '591 patent states that "[t]he guide tube 34 serves to stiffen the catheter body 14 and to help impart twisting motion from the handle to the steering assembly." [Column 4, lines 33-35.]

In view of the foregoing, one of skill in the art would would understand that a "steering center support" is not a coil and, instead, is an element located within the distal portion of catheter that may, for example, be mounted on a coil and connected to a steering wire.

C. Claims 30, 34-39, 50 and 51

Independent claim 30 calls for a combination of elements including, *inter alia*, "a hollow catheter body having a side wall and an aperture," "a ***steering center support*** located within the catheter body" and "adhesive material ... securing the hollow catheter body to the steering center support." Claims 34-39, 50 and 51 depend from independent

claim 30 and the combinations defined thereby include, *inter alia*, the elements recited in claim 30. The cited references fail to teach or suggest such combinations.

1. The Peacock Patent

The Peacock patent discloses a catheter that is advanced over a guidewire or fixed dilation catheter which has been previously positioned. [Column 3, lines 51-67.] It is not steerable and, accordingly, does not include a "steering center support." Nevertheless, the Office Action asserts that the Peackock coil 15, which is merely used to improve the flexibility of the distal portion of the catheter (column 3, lines 2-6), corresponds to the claimed "steering center support." Applicant respectfully submits that, as discussed in Section III-B above, such an interpretation of the claims is unreasonable.

As the Peacock patent fails to teach or suggest each and every element of the combination recited in independent claim 30, applicant respectfully submits that claims 30 and 34 are patentable thereover and that the rejection thereof under 35 U.S.C. § 102 should be withdrawn.

2. The Webster Patent

The Webster patent discloses a device including a catheter body 11, a tip section 12 that is secured to the catheter body, and a puller wire 30 that is used to deflect the tip section. Referring to Figure 4, the puller wire 30 may be secured to the tip section 12 with glue 47. The puller wire 30 extends through a coil 32. The Office Action has taken the position that the Webster coil 32 is a "steering center support." Applicant respectfully submits, however, that one of skill in the art would understand that the coil 32 is not a "steering center support." [See Section III-B above.]

As the Webster patent fails to teach or suggest each and every element of the combination recited in independent claim 30, applicant respectfully submits that claims 30, 34-39, 50 and 51 are patentable thereover and that the rejection thereof under 35 U.S.C. § 102 should be withdrawn.

D. Claims 52-54 and 56-59

Independent claim 52 calls for a combination of elements including, *inter alia*, "a hollow catheter body including proximal member defining a distal region and a distal member defining a distal end with a distal end opening," "a tip member," "***at least one internal component*** located within the catheter body and ***secured to the tip member***" and "adhesive material located within the hollow catheter body such that at least a portion of the adhesive material is in the vicinity of the side wall aperture, ***the adhesive material in the vicinity of the side wall aperture securing the proximal member distal region to the at least one internal component***." Claims 53, 54 and 56-59 depend from independent claim 52 and the combinations defined thereby include, *inter alia*, the elements recited in claim 52. The cited references fail to teach or suggest such a combination.

The Webster patent discloses a catheter that includes a catheter body 11 (which consists of an outer wall 17 and a stiffening tube 18) and a tip section 12 (which consists of a tubing 16) that are connected to one another at a notch 27. A guide coil 32 is secured to the distal portion of the catheter body 11 with glue 38. The distal end of a puller wire 30, which slides through the coil 32, may be secured to the tip section tube 16 with glue 47 that is located near an opening (or notch) 46 in the tip section tube (Figure 4). In an alternative arrangement illustrated in Figure 6, the puller wire 30 is secured to a plastic cap 48 at the distal end of the tip section.

In contrast to the combination defined by independent claim 52, which calls for an "internal component" that is (1) secured to a tip member and (2) secured to a catheter body proximal member, the Webster puller wire 30 is ***only*** secured to the tip section tubing 16 ***or*** to the cap 48. The Webster coil 32 is ***only*** secured to the stiffening tube 18. As such, neither of the puller wire 30 or the coil 32 corresponds to the claimed "internal component." Moreover, to the extent that the Office Action has indicated that the Webster puller wire 30 and coil 32 together form the claimed "internal component," the glue 38 which secures the coil 32 to the catheter body 11 (i.e. the "proximal member") is not

located in the vicinity of the opening 46. The opening 46 is in the tip section 12 and is employed when the puller wire 30 is secured to the tip section tube 16 with glue 47.

As the Webster patent fails to teach or suggest each and every element of the combination recited in independent claim 52, applicant respectfully submits that claims 52-54 and 56-59 are patentable thereover and that the thereof under 35 U.S.C. § 102 should be withdrawn.

E. Claim 65

Independent claim 65 calls for a combination of elements including, *inter alia*, a hollow catheter body including ... a distal member, "a steering center support located within at least the distal member" and "a steering wire having a distal end secured within the distal member." The Berenstein patent fails to teach or suggest such a combination.

The Berenstein patent does not even disclose a steerable catheter, let alone a combination of elements including a "steering center support" and a "steering wire." The Office Action asserts that the Berenstein stylet 120, which is placed within the interior of the catheter when the catheter is being advanced into the vasculature, corresponds to the claims "steering center support." As discussed in column 4, lines 36-52 of the Berenstein patent, the stylet 120 is device which is typically longer than the catheter itself that is used to provide stiffness to the catheter as it is being advanced through a guide catheter and/or over a guidewire. Such a device simply is not a "steering center support," as this term would be understood by one of ordinary skill in the art who had reviewed the present application. [See Section III-B above.] The Berenstein patent also fails to teach or suggest the use of a "steering wire."

As the Berenstein patent fails to teach or suggest each and every element of the combination recited in independent claim 65, applicant respectfully submits that claim 65 is patentable thereover and that the rejection thereof under 35 U.S.C. § 102 should be withdrawn.

IV. NEWLY PRESENTED CLAIMS 70-72

Newly presented claims 70-72 depend from independent claim 30 and, accordingly, are patentable for at least the same reasons as independent claim 30.

Newly presented claims 73 depends from independent claim 52 and, accordingly, is patentable for at least the same reasons as independent claim 52.

V. CLOSING REMARKS

In view of the foregoing, it is respectfully submitted that the claims in the application are in condition for allowance. Reexamination and reconsideration of the application, as amended, are respectfully requested. Allowance of the claims at an early date is courteously solicited.

If for any reason the Examiner finds the application other than in condition for allowance, the Examiner is respectfully requested to call applicant's undersigned representative at (310) 563-1458 to discuss the steps necessary for placing the application in condition for allowance.

The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 50-0638. Should such fees be associated with an extension of time, applicant respectfully requests that this paper be considered a petition therefor.

Respectfully submitted,

2/25/04
Date

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